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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/578,458	05/22/00	BALLINGER	D 28110/36479

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EXAMINER	
SEHARASEYON, J	
ART UNIT	PAPER NUMBER
1647	11

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

T Lowry

Office Action Summary	Application No.	Applicant(s)	
	09/578,458	BALLINGER ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14-16,20 and 27-29* is/are pending in the application.

4a) Of the above claim(s) *14-16 and 27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-10 and 20 in Paper No: 10 (8/14/01) is acknowledged. The traversal is on the ground(s) that Groups I and III can be searched and examined simultaneously. This is not found to be persuasive because claims of Group III are directed to the collection of sequence information and not the nucleotide molecules. In addition, the claims of Group II do not involve the use of nucleotides but are a method of detection. The restriction requirement is deemed proper and therefore made FINAL.

Claims 14-16 and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10 (8/14/01).

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: Nucleotide encoding Interleukin-1 Hy2 polypeptide.

Drawings

3. The drawings filed on 5/22/00 are acceptable subject to correction of the informalities indicated on the attached "Notice of Draftperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required.

Claim Objection

5. Claim 20 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, claim 20 has not been further treated on the merits. Furthermore, claim 20 is dependent on cancelled claim 11.

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6a. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 2 recite a "mature protein coding sequence" or "mature amino acid sequence"; however, the instant specification fails to describe that portion of a protein which is the "mature" portion. Applicant is claiming a very specific species which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of a "mature portion of a protein" cannot be predicted on the basis of the amino acid sequence of the entire protein since the protein may be proteolytically cleaved *in vivo*, as well as being differentially processed based

on which tissue the protein is expressed. The claims are directed to a species of protein, the structure of which cannot be determined or predicted from full-length amino acid sequence and the specification does not evidence isolation or conception of the structure of the "mature portion of a protein"; therefore, the specification does not provide an adequate written description of a mature protein, and thus the claimed invention, to the extent that it reads upon mature protein, was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Further, the structure of the "mature" protein will be host cell specific; i.e. *E. coli* will produce a form of the protein which is the "mature" form in that host whereas an insect host may produce a different form which will also be a "mature" form. Therefore, the instant specification fails to describe "mature" because this is a specific structure for which there is insufficient evidence to establish that the invention was described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6b. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The specification discloses polynucleotide of SEQ ID NO: 1,12 or 14 and the polynucleotide encoding a polypeptide with IL-1 HY2 activity. This meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the specification does not disclose any polynucleotide consisting of allelic variant of a polynucleotide comprising the polynucleotide sequence of SEQ ID NO: 1,12 and 14 or polynucleotide encoding a polypeptide with IL-1 HY2 activity. The claims as written, however, encompass polynucleotide sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claim 5. The specification does not provide written to support the genus encompassed by the instant claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (*See Vas-Cath* at page 1116).

With the exception of an isolated polynucleotide of SEQ ID NO: 1,12, 14 and the polynucleotide encoding a polypeptide with IL-1 HY2 activity the skilled artisan cannot envision all the detailed chemical structure of the claimed polypeptides, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only an isolated polynucleotide of SEQ ID NO: 1,12, 14 and the polynucleotide encoding a polypeptide with IL-1 HY2 activity, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. As a result, it does not appear that the inventors were in possession of various polynucleotide sequences set forth in claim 5.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

6c. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotide of SEQ ID NO: 1,12 or 14 and polynucleotide encoding a polypeptide with IL-1 HY2 activity does not reasonably provide enablement for any polynucleotide consisting of an allelic variant of a polynucleotide comprising the polynucleotide sequence of SEQ ID NO: 1,12 and 14 or polynucleotide encoding a polypeptide with IL-1 HY2 activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotide of SEQ ID NO: 1,12 or 14 and

polynucleotide encoding a polypeptide with IL-1 HY2 activity does not reasonably provide enablement for any polynucleotide consisting of allelic variant of a polynucleotide comprising the polynucleotide sequence of SEQ ID NO: 1,12 and 14 or polynucleotide encoding a polypeptide with IL-1 HY2 activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The instant claims read on allelic variant of a polynucleotide comprising the polynucleotide sequence of SEQ ID NO: 1,12 and 14 or polynucleotide encoding a polypeptide with IL-1 HY2 activity. However, other than polynucleotide sequence of SEQ ID NO: 1,12 and 14 or polynucleotide encoding a polypeptide with IL-1 HY2 activity, the specification as filed fails to disclose any other polypeptide sequences

Despite knowledge in the art for producing allelic variants of a given polynucleotide, the specification fails to provide any guidance regarding the changes/modifications contemplated and yet retain the function of the protein claimed. Furthermore, detailed information regarding the structural and functional requirements of the disclosed protein is lacking. Although it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a protein's structure and function from mere sequence data remains an elusive task. Therefore, predicting which allelic variants would retain the functions of the protein is well outside the realm of routine experimentation. Thus, undue amount of experimentation would be required to generate changes/modifications contemplated and yet retain the function of the proteins claimed.

Applicants have not taught how one of skill in the art would use the full scope of polynucleotide sequences encompassed by the invention of claim 5. The specification as filed does not sufficiently teach one of skill in the art how to make and/or use the full scope of the claimed sequences. The amount of experimentation required to make and/or use the full scope of the claimed sequences would require trial and error experimentation to determine the functional sequences. Given the breadth of claim 5 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior art of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7a. Claims 1 and 2 are indefinite because the elements recited in the claims do not constitute proper Markush groups. The claims are indefinite in the alternative use of "and/or" because it is not clear what controls which of these limitation. See MPEP § 2173.05 (h). Furthermore it is unclear what nucleotide is claimed in Claim 1c. In addition, Applicants need to amend claim 2 to recite the claim in either singular or plural. Claims 3-10 are rejected insofar as they depend on claims 1 and 2.

7b. Claims 1 and 2 are rejected as vague and indefinite for reciting the term "mature protein coding sequence" or "mature amino acid sequence", because the term "mature protein coding sequence" or "mature amino acid sequence" is not defined in the specification. This is because the structure of a "mature portion of a protein" cannot be predicted on the basis of the amino acid sequence of the entire protein since the protein may be proteolytically cleaved *in vivo*, as well as being differentially processed based on which tissue the protein is expressed. Claims 3-10 are rejected insofar as they depend on claims 1 and 2.

7c. Claim 3 is rejected as vague and indefinite for reciting the phrase "stringent conditions". Stringency is a relative term, and the art does not recognize a single set of conditions as "stringent". The specification also does not provide an unambiguous definition for the term (several conditions are described in page: 10, lines 19-27). In the absence of a recitation of clear hybridization conditions, claim 3 fails to define the metes and bounds of the claim. Claims 4,5 and 8-10 are rejected insofar as they depend on claim 3.

7d. Claim 3 is rejected as vague and indefinite for reciting the term "IL-1 Hy2 activity". It is unclear how one might isolate a polynucleotide encoding a polypeptide with a specific activity. Claims 4,5 and 8-10 are rejected insofar as they depend on claim 3.

7e. Claim 5 is rejected as vague and indefinite for reciting the term "allelic variant", because the term "allelic variant" is not defined in the specification. This is because an allelic variant may encompass a single amino acid change or several amino acid changes and it is unclear what "allelic variants" are encompassed in this claim. Claim 6 is rejected insofar as it depends on claim 5.

8. No claims are allowable but are apparently free of prior art.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
November 5, 2001

JEFFREY STUCKER
PRIMARY EXAMINER